JUL 19 2011

9 510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92)

Pursuant to Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, Penumbra Inc. is providing the summary of Substantial Equivalence for the Neuron™ MAX System.

9.1 Sponsor/Applicant Name and Address

Penumbra, Inc.
1351 Harbor Bay Parkway
Alameda, CA 94502, USA

9.2 Sponsor Contact Information

Michaela Mahl
Regulatory Program Manager
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9.3 Date of Preparation of 510(k) Summary

June 24, 2011

9.4 Device Trade or Proprietary Name

Neuron™ MAX System

9.5 Device Classification

Regulatory Class:	II
Classification Panel:	Cardiovascular
Classification Name:	Percutaneous Catheter
Regulation Number:	21 CFR § 870.1250
Product Code:	DQY

9.6 Predicate Devices

510(k) Number / Clearance Date	Name of Predicate Device	Name of Manufacturer
K070970 / 17Aug2007	Neuron Intracranial Access System 053, Model 5F/6F	Penumbra, Inc.
K082290 / 31Oct2008	Neuron Delivery Catheter 070	Penumbra, Inc.
K083125 / 21Nov2008	Neuron Select Catheter 070	Penumbra, Inc.

9.7 Device Description

The Neuron MAX System is an additional configuration to the currently available Neuron Intracranial Access System. The Neuron Max System provides a larger lumen to assist in utilizing contrast injections to further optimize anatomical visualization while maintaining a flexible distal tip. This larger lumen also accommodates larger therapeutic devices like the Penumbra System® and Penumbra Coil 400™ devices. The devices are provided sterile, non-pyrogenic, and intended for single use only.

9.8 Intended Use

The Neuron™ MAX System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

9.9 Summary of Non-Clinical Data

As required under Section 12, Part (a)(i)(3A) of the Safe Medical Devices Act of 1990, a summary of any information regarding safety and effectiveness of the device follows.

Included in this section are descriptions of the testing's, which substantiates the safe and effective performance of the Neuron MAX System as well as its substantial equivalence to the predicate devices:

- Biocompatibility
- Design Verification (Bench-Top Testing)
- Animal Study

The subject Neuron MAX System met all established requirements.

9.9.1 Biocompatibility Testing

Biocompatibility tests conducted with the Neuron MAX System were selected in accordance with ISO 10993 -1 guidelines (Biological Evaluation of Medical Devices) for limited duration (<24 hours), external communicating devices, contacting circulating blood. All studies were conducted pursuant to 21 CFR, Part 58, Good Laboratory Practices. In summary, non-clinical testing found the Neuron MAX System to be biocompatible according to the requirements of ISO 10993 requirements. The following tests were performed:

Test	Method	Results
In Vitro Cytotoxicity	ISO Elution Test (MEM Extract)	No evidence of cell lysis or toxicity
Sensitization	ISO Maximization Test for Delayed Hypersenitivity	Non-Sensitizing
Acute Intracutaneous Reactivity (Irritation)	ISO Intracutaneous (Intradermal) Injection Test	No evidence of irritation
Acute Systemic Toxicity	ISO Acute Systemic Injection Test	No evidence of systemic toxicity
Rabbit Pyrogen Study	USP Material-Mediated Rabbit Pyrogen Test	No evidence of material-mediated pyrogenicity
Hemo-compatibility		
- In Vitro Hemolysis	ASTM Methode (Extraction & Direct Contact)	Non-Hemolytic
- In Vitro Coagulation (PT, PTT)	Prothrombin Time (PT) Assay	Coagulation times are not significant different than corresponding control
	Partial Thromboplastin Time (PTT) Assay	Non-Thrombogenic
Complement Activation	C3a and SC5b-9 through Enzyme Assay	No greater biological response than corresponding control
Dog Thrombogenicity	Thrombogenicity Study in Dogs - ISO	Non-Thrombogenic
Genotoxicity		
- Mouse Lymphoma	Mouse Lymphoma Mutagenesis Assay - ISO	Non-Mutagenic
- Ames Mutagenicity	Ames Test	Non-Mutagenic
- In Vivo Mouse Micronucleus	Micronucleus Assay - ISO	Non-Clastogenic

9.9.2 Bench-top Testing

The physical and mechanical properties of the Neuron MAX System were assessed using standard test methods and pre-determined acceptance criteria. The following tests were performed:

Test / Test Subject	Attribute	Result
Pouch Seal	Pouch Seal Strength	Met established criteria
Dimensional / Visual Inspection	These evaluations confirm that the units used in this Design Verification testing meet all inspection criteria for release of finished goods (clinically acceptable) product.	Met established criteria
Simulated Use [Intracranial Access & Vessel Access Entry Performance]	These evaluations confirm that the units used in this Design Verification testing meet all inspection criteria for release of finished goods (clinically acceptable) product.	Met established criteria
MAX 088 Delivery Catheter / Dilator	Hub /Shaft & Mid-shaft or Shaft Tensile Strength	Met established criteria
6F Select Catheter	Hub /Shaft & Mid-shaft Tensile Strength	Met established criteria
MAX 088 Delivery Catheter / 6F Select Catheter / Dilator	Hub Air Aspiration	Met established criteria
	Burst Test	Met established criteria
MAX 088 Delivery Catheter	Particulate Testing (Hydrophilic Coating)	Met established criteria
MAX 088 Delivery Catheter / 8F Sheath compatibility	Friction Force	Met established criteria
MAX 088 Delivery Catheter / 6F Select Catheter compatibility		Met established criteria
6F Select Catheter / 0.038" Guidewire compatibility		Met established criteria
MAX 088 Delivery Catheter / Neuron MAX Dilator compatibility		Met established criteria
Neuron MAX Dilator / 0.038" Guidewire compatibility		Met established criteria
MAX 088 Delivery Catheter / 6F Select Catheter	Flow Rate	Met established criteria
MAX 088 Delivery Catheter / 6F Select	Elongation to Failure	Met established criteria

Test / Test Subject	Attribute	Result
Catheter / Dilator		
MAX 088 Delivery Catheter / 6F Select Catheter / Dilator / RHV / HVA	Corrosion	Met established criteria
MAX 088 Delivery Catheter / 6F Select Catheter	Torsion	Met established criteria

The results of the tests appropriately address the physical and mechanical performance expectations of the device. This is further supported by the surgical handling and performance results reported in the *in vivo* study. Based on these overall results, the physical and mechanical properties of the Neuron MAX System are acceptable for the intended use and substantially equivalent to the predicate devices.

9.9.3 Animal Study

An animal study was conducted to evaluate the safe use of the Neuron MAX System in a swine model. The study concluded that:

- No vessel injury was noted on the final angiograms following the vessel response procedure.
- No abnormal gross or histology findings were noted in test vessel segments.
- The use of the Neuron MAX System resulted in no significant vascular response in these experimental conditions.

9.9.4 Summary of Substantial Equivalence

The Neuron MAX System is substantially equivalent to the predicate devices with regard to intended use, operating principle, design concept, materials, shelf-life, packaging and sterilization processes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Penumbra, Inc.
c/o Ms. Michaela Mahl
Regulatory Program Manager
1351 Harbor Bay Parkway
Alameda, CA 94502

Re: K111380
Trade/Device Name: Neuron™ MAX System
Regulation Number: 21 CFR 870.1250
Regulation Name: Catheter, Percutaneous
Regulatory Class: Class II
Product Code: DQY
Dated: June 24, 2011
Received: June 27, 2011

JUL 19 2011

Dear Ms. Mahl:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

10 Statement of Indication for Use

Indications for Use

510(k) Number (if known): K111380

Device Name: Neuron™ MAX System

Indications for Use:

The Neuron MAX System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over The Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K111380